REMARKS

The Official Action mailed October 26, 2007 has been carefully considered. Reconsideration and allowance of the subject application, as amended, are respectfully requested.

Claim 3' has been canceled to rectify the inadvertent error in numbering two successive claims as "3". New claim 20 has been added and recites the same subject matter as former claim 3'.

Rejection under 35 U.S.C § 112

Claims 1 through 14 were rejected under 35 U.S.C § 112 as being unenabling for a cure or prevention of posterior segment diseases. Claim 1 has been amended to recite ". . . in a therapeutically effective amount to ameliorate and/or stabilize said posterior segment disease." Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C § 102

Claims 1, 2, 3, 5, 6, 9, 10 and 11 were rejected under 35 U.S.C § 102(b) as being anticipated by United States Patent No. 5,723,131 to Schultz (Schultz '131).

The Office Action states that Schultz '131 teaches the use of a polymeric hydrogel comprising desferrioxamine as the medicinal agent to kill or inhibit the growth of bacteria. The Office Action further states that desferrioxamine controls bacteria that are known to cause inflammation in the retina. Exemplary posterior segment diseases are provided in paragraph 1 on page 4 of the present application. Bacterial infection is outside of the class of posterior segment diseases recited in the pending claims. Thus Schultz '131 fails to disclose each and every element of claim 1. As each of claims 2, 3, 5, 6, 9, 10 and 11 depend either directly or indirectly from claim 1, they are patentable over Schultz '131 for at least the above mentioned reason. Withdrawal of the rejection is respectfully requested.

Rejection under 35 U.S.C § 103

Claims 1 through 14 were rejected under 35 U.S.C § 103(a) as being unpatentable over Schultz '131 in view of United States Patent Application Publication 2002/0197300 to Schultz

(Schultz 300), in view of PCT publication WO03/0244200 to Alheim et al (Alheim) and in view Gerkowicz and Prost, "Studies On the Use of Desferrioxamine in an Experimental Ocular Siderosis Produced by Extrabulbar Administration of Iron" (Gerkowicz).

The Office Action states that the motivation to combine the four references "is the ability to treat posterior segment disease by the use of a contact lens, which at the same time corrects the subject's vision." Applicant finds that this is simply a paraphrasing of the subject matter of claim 11 in the present application and does not see how one of ordinary skill in the art would have been motivated to do so absent the teaching of the present application.

Applicant disagrees that would have been obvious to combine the four cited references. For instance, applicant believes that the cited references fail to show a reasonable expectation of success and in fact would lead a skilled practitioner away from the claimed invention. Gerkowicz discloses the transconjuctival injection of desferrioxamine into the eye for the removal of iron. The office action points to page 104, second column, first paragraph, for supporting the proposition that desferrioxamine can reach the posterior segment of the eye. The same paragraph states that "the penetration of desferrioxamine into the eyeball is very limited and its ability to remove iron already present in the retina or choroid is relatively small. For this reason, the drug should be applied as early as possible, before iron has invaded the ocular tissues." The second paragraph in the same column further states that the administration of desferrioxamine was sufficient "on the condition that the drug is administered in the direct vicinity of the foreign body located in the orbit." These teachings would instruct the skilled practitioner that a) the drug must be injected; b) the drug must be administered in the direct vicinity of the location to be treated; and c) the drug must be administered in large doses (30mg.). With all of these factors pointing to how difficult it is to deliver a drug to the posterior segment, one would not expect a reasonable chance of success in treating the posterior segment with a drug that is being passively released from a polymeric hydrogel positioned on the eye, as claimed. Applicant fails to see where the other three references provide any evidence refuting Gerkowicz's teaching of a lack of reasonable expectation of success. For example, in listing possible methods of administration, Alheim teaches that formulations "may be administered, periocularly, e.g. retrobulbarly or sub-tenonly, or subconjuctivally in a variety of ways including

injection, trocar etc." (Alheim at page 8 lines 19 through 20 and 28 through 30.) If Alheim had contemplated a method as elegant as passive delivery via a hydrogel, it certainly would have been mentioned along with these invasive methods. Given the teachings of Alheim and Gerkowicz it is clear that there would be no reasonable expectation of success if one were to attempt to deliver a drug to the posterior segment from a hydrogel positioned on the eye as recited in amended claim 1. Withdrawal of the rejection under 35 U.S.C § 103 is respectfully requested.

Double Patenting

Claims 1 through 14 were provisionally rejected under 35 U.S.C § 101 as claiming the same invention as that of claims 1 through 19 of co-pending Application No. 10/971,997.

The test for double patenting under 35 U.S.C § 101 is whether a claim in the ('997 Application) application could be literally infringed without literally infringing a corresponding claim in the patent. The scope of the claims in the pending application is greater, in some respects, than that of co-pending Application No. 10/971,997. Independent claims 1, 24 and 27 of the '997 application each recite, in part, an anti-angiogenesis compound. This element is not recited in the claims of the present application and therefore the claims of the instant application may, in some cases, be infringed where the claims in '997 application would not. Applicant respectfully requests withdrawal of the provisional rejection.

Rejections under Non Statutory Obviousness Type Double Patenting

Claims 1 through 14 of the present application were found to be unpatentable over claims 1, 2, 4, 5, 9 - 13 and 16 – 20 of the United States Patent No. 7,169,406 (Schultz '406) in view of United States Patent No. 6,410,045 (Schultz '045). The office action quotes Schultz '045 as stating that the "use of conventional hydrogel contact lenses containing various medications is known in the art." The Examiner states that this obviates the use of an anti-VEGF agent in the instant hydrogel contact lens. The applicant fails to see how this broad statement in Schultz '045 would suggest to one skilled in the art that an anti-VEGF agent might be useful in a contact lens. Applicant can find no teaching in the cited art that would even suggest that it might be obvious to try to deliver a drug via a polymeric hydrogel for the treatment of posterior segment disease.

Absent a motivation to treat posterior segment disease using this mechanism, there would be no reason to substitute an anti-VEGF agent for an anti-inflammatory. Therefore, as there is no teaching provided that would suggest the use of an anti-VEGF agent in a contact lens, and given the extremely low expectation of success in treating posterior segment disease, as stated above, the present claims are patentable over the Schultz '406 reference. Withdrawal of the rejection is respectfully requested.

ADDITIONAL NON STATUTORY DOUBLE PATENTING REJECTIONS

The Office Action also includes additional provisional rejections on the grounds of non statutory obviousness type double patenting. Applicant requests that these rejections be kept in abeyance until prosecution of the instant case has been concluded.

Having dealt with all the objections raised by the Examiner, it is respectfully submitted that the present application, as amended, is in condition for allowance. Thus, early allowance is earnestly solicited.

If the Examiner desires personal contact for further disposition of this case, the Examiner is invited to call the undersigned Attorney at 603.668.6560.

In the event there are any fees due, please charge them to our Deposit Account No. 50-2121.

Respectfully submitted,

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